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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/426,931	10/22/1999	WOLFGANG-REINHOLD KNAPPE	BMID9826US	2537

7590 09/20/2005

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EXAMINER
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CROSS, LATOYA I

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 09/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/426,931

Applicant(s)

KNAPPE, WOLFGANG-REINHOLD

Examiner

LaToya I. Cross

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 June 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 41-48 and 56-62 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 61 and 62 is/are allowed.
- 6) ☒ Claim(s) 41-43, 46-48 and 56-60 is/are rejected.
- 7) ☒ Claim(s) 44 and 45 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

This Office Action is in response to Applicants' remarks filed on June 30, 2005. Claims 41-48 and 56-62 are pending.

#### *Claim Rejections - 35 USC § 103*

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Claims 41-43, 46-48 and 56-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over US patent 5,846,837 to Thym et al in view of US patent 2,063,987 to Dreyfus.

Thym et al disclose a diagnostic device comprising a support layer (2), a detection layer (3) and a network layer (4), which is an overlay layer. The detection layer (3) contains reagents which can be observed and measured and the signal formation is visible through the supporting layer, which may be transparent (col. 6, line 64 – col. 7, line 3). The device may have two detection layers (3), as recited in claims 46 and 59 (col. 11, lines 21-22). The network (4) is a material that is not capillary active, such as monofilament fabrics. The monofilament fabric may be made hydrophilic by treatment with a wetting agent. The network overlay (4) is attached to support layer (2) by means of spacers (10). Cover layers (5) are attached to the support (2) and the network overlay (4) in a manner such that they cover the area of the network overlay that extends beyond the detection layer (3). With respect to claims 47, 47 and 58, Thym et al disclose that where large volumes of sample are disposed onto the sample application area (7), the void spaces under cover layers (5) are filled first, so that no excess fluid is taken up by the detection layer. With respect to claim 56, Thym et al disclose that the network overlay (4) extends beyond detection layer (3) and is covered by cover layers (5), as shown in figure 4 of the reference.

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Thym et al differ from the instant invention in that while the reference teaches that the network overlay (4) may be treated with a wetting agent, no particular wetting agent is disclosed.

Dreyfus '987 teaches that fatty acid sarcosine are good wetting agents. At col. 2, lines 20-30, Dreyfus teaches higher fatty acid radicals, such as those containing more than 8 carbon atoms are suitable. Dreyfus specifically teaches the oleic acid radical as an example where valuable results may be obtained. The fatty acid sarcosines are particularly used in wet treating textile materials such as fabric-like material.

It would have been obvious to one of ordinary skill in the art to use the oleoyl sarcosine wetting agents taught by Dreyfus in the test strips of Thym et al to provide better wetting properties to the fibrous pads and allow sample to be up taken more efficiently.

#### *Allowable Subject Matter*

3. Claims 61 and 62 are allowed.
4. Claims 44 and 45 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The prior art of record fails to teach two overlay elements, as recited in claims 44 and 61, wherein the overlay elements face one another and whose parts are displaceable from the test strip.

#### *Response to Arguments*

5. Applicant's arguments filed June 30, 2005 have been fully considered but they are not persuasive. With respect to the obviousness rejection over Thym in view of Dreyfus, Applicants argue that 1) the instant invention is commonly owned with the Thym reference and thus Thym is not available as prior

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art and 2) Thym was not published before the instant invention and thus Thym is not available as prior art against the instant claims.

With respect to Applicants' assertion that the Thym reference and the instant invention were commonly owned at the time the invention was made, the Examiner notes that 35 USC 103(c) states that where the subject matter developed qualifies as prior art only under 102(e), 102(f) or 102(g), patentability shall not be precluded if the claimed invention and the subject matter were commonly owned at the time the invention was made. In the instant case, the Thym reference has a publication date of December 8, 1998. The instant application has an effective filing date of October 22, 1999. Thus, the Thym reference qualifies under 35 USC 102(a). Applicants may not overcome the rejection based on Thym and the provisions of 35 USC 103(c), since section 103(c) does not apply in the instant case. See MPEP 706.02(l)(1).

With respect to Applicants' assertion that Thym is not available as prior because it was not published before the instant invention, the Examiner notes the following: The instant invention is given an effective filing date of October 22, 1999 due to the foreign priority NOT having been perfected. To overcome the obviousness rejection, Applicants must disqualify the Thym reference from section 102(a). MPEP 706.02(b) states that such would require 1) an affidavit or declaration under 37 CFR 1.131 (to antedate the Thym reference), or 2) an affidavit or declaration under 37 CFR 1.132 showing that the reference invention is not "by another", or 3) by perfecting a claim to priority under 35 USC 119(a)-(d). Option (3) will not be sufficient as the Thym reference has a related document with a publication date prior to that of Applicants' foreign priority date.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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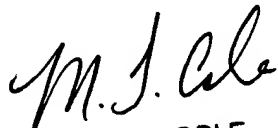
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LaToya I. Cross whose telephone number is 571-272-1256. The examiner can normally be reached on Monday-Friday 8:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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MONIQUE T. COLE  
PRIMARY EXAMINER